(5)

No. 03-779

Supreme Court, U.S.
FILED
DEC 23 2003
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

v.

THE KROGER CO., *ET AL.*

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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MOTION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

Pursuant to Rule 37.2 of the Rules of this Court, the Pharmaceutical Research and Manufacturers of America (PhRMA) hereby moves for leave to file the accompanying brief as *amicus curiae* in support of petitioner. PhRMA's members invest billions of dollars each year to discover and develop new medicines, and are responsible for almost all of the innovative medicines that have been approved for use in the United States over the past several decades. As a result, PhRMA and its members have a large stake in intellectual property rights and the rules governing the resolution and settlement of patent disputes. Accordingly, they view the question presented by the petition in this case – whether certain patent settlements are subject to the *per se* rule under section 1 of the Sherman Act – as a matter of critical

importance. PhRMA participated in this action as *amicus curiae* in the court of appeals.

Petitioner has consented to the filing of the accompanying *amicus* brief; its counsel's written consent so stating has been submitted to the Clerk. Likewise, respondents Kroger Company, Albertson's, Inc., Hy-Vee, Inc., The Stop & Shop Supermarket Company, Walgreen Company, Eckerd Corporation, Aventis Pharmaceuticals, Inc. (formerly Hoechst Marion Roussel, Inc.), CVS Meridian, Inc., and Rite-Aid Corporation have consented, and their written consents have been submitted to the Clerk. Respondents Charles Zuccarini, Joseph D'Esposito, Shirlean Glover, Larry S. Sizemore, Albert Eirich, Aetna, Inc., and Cobalt Corporation have refused consent. Respondents Duane Reade, Inc., Louisiana Wholesale Drug Company, and Eugenia Wynne Sams have not responded to PhRMA's attempts to obtain their written consent.

Respectfully submitted,

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BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's

[1] Pursuant to Rule 37.6, PhRMA states that no counsel for a party authored this brief in whole or in part, and no person or entity, other than PhRMA or its members, made a monetary contribution to the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org/whoweare/members/. Hoechst Marion Roussel, Inc. (now Aventis Pharmaceuticals Inc.), which was a defendant below and settled while the case was on appeal (*see* Pet. App. 14a n.9), is a member of PhRMA.

members invested more than $32 billion in 2002 to discover and develop new medicines. They are responsible for almost all of the innovative medicines that have been approved for use in the United States over the past several decades.

Intellectual property principles, including patent rights and the rules governing patent litigation and settlement, are of critical importance to PhRMA's members and to their research and development efforts. PhRMA participated in this case as an *amicus* in the court of appeals.

STATEMENT OF THE CASE

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires approval by the Food and Drug Administration (FDA) before a new drug may be marketed. *See* 21 U.S.C. § 355(a). A research-based company seeks initial approval by submitting a full new drug application (NDA), which contains extensive data from controlled clinical studies, animal tests, and laboratory investigations. *See* 21 U.S.C. § 355(b). A generic company may obtain approval of a copy of the innovator's drug by filing an abbreviated new drug application (ANDA), which contains much more limited information. *See* 21 U.S.C. § 355(j).

The FFDCA establishes complex procedures governing patent disputes between innovator and generic companies. *See* 21 U.S.C. § 355(j). These procedures are intended to allow the courts to resolve patent disputes before potentially infringing generic products enter the market. This is accomplished by staying FDA approval of the generic company's ANDA for 30 months while patent litigation is pending. The law also provides an incentive for generic companies to challenge patents in the form of 180 days of

exclusive ANDA marketing rights for the first company to submit such a challenge.[2]

This case arises out of patent litigation between an innovator company, Hoechst Marion Roussel, Inc. (HMR), and a generic company, petitioner Andrx Pharmaceuticals, Inc. (Andrx), which filed an ANDA for a copy of one of HMR's drugs, Cardizem® CD. When it appeared that the district court might not issue a decision before expiration of the 30-month stay, the parties entered into a stipulation rather than litigating a preliminary injunction motion that HMR was prepared to file. Pet. App. 97a. Under the stipulation, Andrx agreed to maintain the status quo while the litigation was pending, and HMR agreed to provide certain licensing rights and make certain payments to Andrx, among other things. The parties ultimately entered into a final settlement, pursuant to which Andrx agreed not to sell the original formulation of its product, and HMR agreed not to sue with respect to a noninfringing reformulation. When FDA approved the reformulated product, Andrx entered the market. Following an investigation, the Federal Trade Commission (FTC) determined that the stipulation did not delay market entry of a generic version of Cardizem CD by Andrx or any other manufacturer. *See* 66 Fed. Reg. 18636, 18638 (Apr. 10, 2001).

Respondents are plaintiffs in a number of class actions and individual cases alleging that the stipulation between Andrx and HMR violated the antitrust laws. These

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[2] Congress recently amended both the 30-month stay and 180-day exclusivity provisions of the law in sections 1101 and 1102 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 1936 (2003). These changes do not affect the continued importance of the question presented by the petition in this case or the need for this Court's review.

cases were consolidated in the United States District Court for the Eastern District of Michigan. The district court ruled that the stipulation constituted a *per se* violation of section 1 of the Sherman Act, 15 U.S.C. § 1. Pet. App. 34a-35a. On interlocutory appeal, the United States Court of Appeals for the Sixth Circuit affirmed. Pet. App. 1a, 4a.

SUMMARY OF THE ARGUMENT

The petition should be granted because it presents an important question on which there is a conflict between the circuits. Patent rights are the critical foundation for continued pharmaceutical innovation, and thus for the discovery and development of new medicines for patients with serious and life-threatening illnesses such as cancer and Alzheimer's disease. Patent disputes between innovator and generic companies are common and often involve "blockbuster" medicines used by millions of persons and with sales of billions of dollars. The rules governing settlement of these disputes are therefore critically important not only to the parties but to the entire healthcare sector. The Sixth Circuit erred by subjecting the settlement to the *per se* rule rather than undertaking a rule of reason analysis that would take into account the substantial procompetitive features of the stipulation at issue here. Its decision directly conflicts with a more recent decision of the Eleventh Circuit involving the same issues, *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1310-11 (11th Cir. 2003). This Court should grant the petition to resolve the conflict.

ARGUMENT

Patent rights are absolutely vital to promoting pharmaceutical innovation.[3] Indeed, according to the FTC, innovation in the pharmaceutical industry "showcases the patent system's benefits" because it prevents low-cost free-riding by generics on the high upfront costs incurred by research-based companies to demonstrate safety and effectiveness as required for FDA approval of a full NDA.[4] Without effective patent and other intellectual property protections, industry could not make the substantial investments required to discover and develop new medicines.

While most generic drug applications seek approval only after the expiration of relevant patents, an increasing number in recent years include challenges to patents and request approval before patent expiration. An FTC study published in 2002 found that approximately 20 percent of ANDAs filed between 1998 and 2000 included patent challenges, a figure that had "increased substantially" over prior periods.[5] The drugs subject to patent challenges "represent some of the largest drug products as measured by annual sales, including [many] so-called 'blockbuster' drugs."[6]

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[3] *See, e.g.*, Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries* (2002) (at http://www.dallasfed.org/news/research/02science_grabowski.pdf).

[4] FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, at 14 (Oct. 2003) (at http://www.ftc.gov/os/2003/10/innovationrpt.pdf).

[5] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 10 (July 2002) (at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

[6] *Id.*

The stakes in these patent disputes are large: many of the drugs in issue have annual sales of more than $1 billion. Not surprisingly, the parties to pharmaceutical patent litigation frequently consider at least the possibility of settlement, and a number of cases have in fact been settled. Antitrust challenges to these settlements may arise in virtually any federal district court, and often challenges to the same settlement are filed in courts within the jurisdiction of different courts of appeals. It is therefore particularly important that the rules applicable to these settlements be well-established and uniform.

The Sixth Circuit erred in condemning a *bona fide* settlement of patent litigation as a *per se* violation of section 1 of the Sherman Act. This Court has long recognized that settlements of intellectual property disputes raise fundamentally different concerns from other types of agreements between competitors. *See, e.g., Standard Oil Co. (Indiana)* v. *United States*, 283 U.S. 163 (1931). The simple fact is that a presumptively valid patent operates to exclude others from the field of invention as claimed in the patent. A settlement of patent litigation involving a compromise of those rights in any respect will have procompetitive features that must be taken into account through a rule of reason analysis under section 1. Blanket condemnation under the *per se* rule ignores the economic and legal context in which these settlements arise, and it is inconsistent with this Court's antitrust jurisprudence. *See, e.g., California Dental Ass'n* v. *FTC*, 526 U.S. 756, 769-71 (1999); *Northwest Wholesale Stationers, Inc.* v. *Pacific Stationery & Printing Co.*, 472 U.S. 284, 296-98 (1985).

Shortly after the Sixth Circuit decided this case, the Eleventh Circuit reached the opposite result in a case raising precisely the same issue, *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d at 1310-11. The court in *Valley Drug* correctly rejected the *per* se approach, and observed that the exclusionary right granted by a patent must

be taken into account in evaluating the lawfulness of a settlement under section 1. *See id.* In view of the substantial and continuing importance of the issue, this Court should grant the petition to resolve the direct conflict between the circuits.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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December 2003